

Exhibit 3

In re Zetia (Ezetimibe) Antitrust Litigation

Case No: 2:18-md-2836

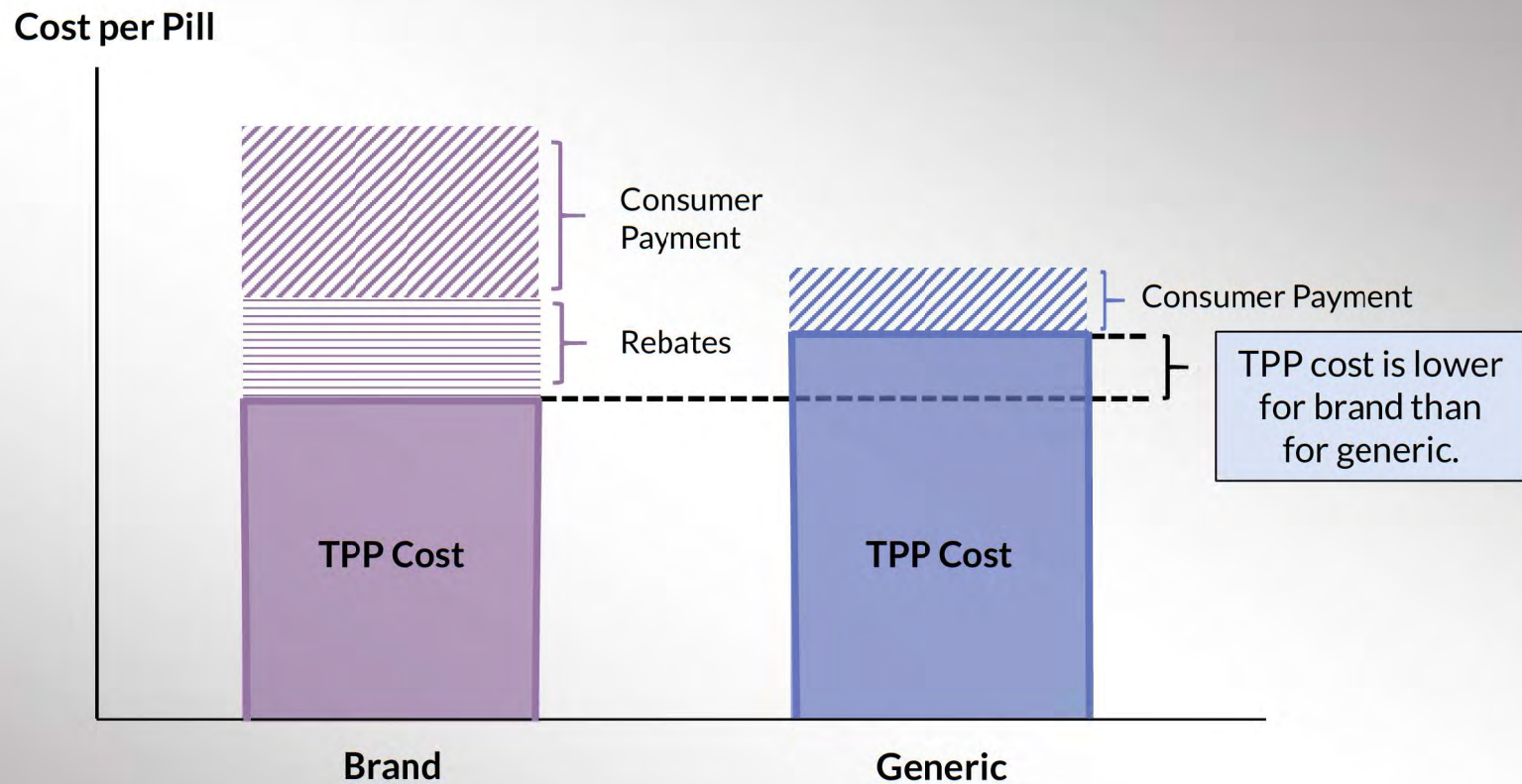
Dr. James Hughes, Ph.D.

May 1, 2020

Confidential – Subject to Protective Order

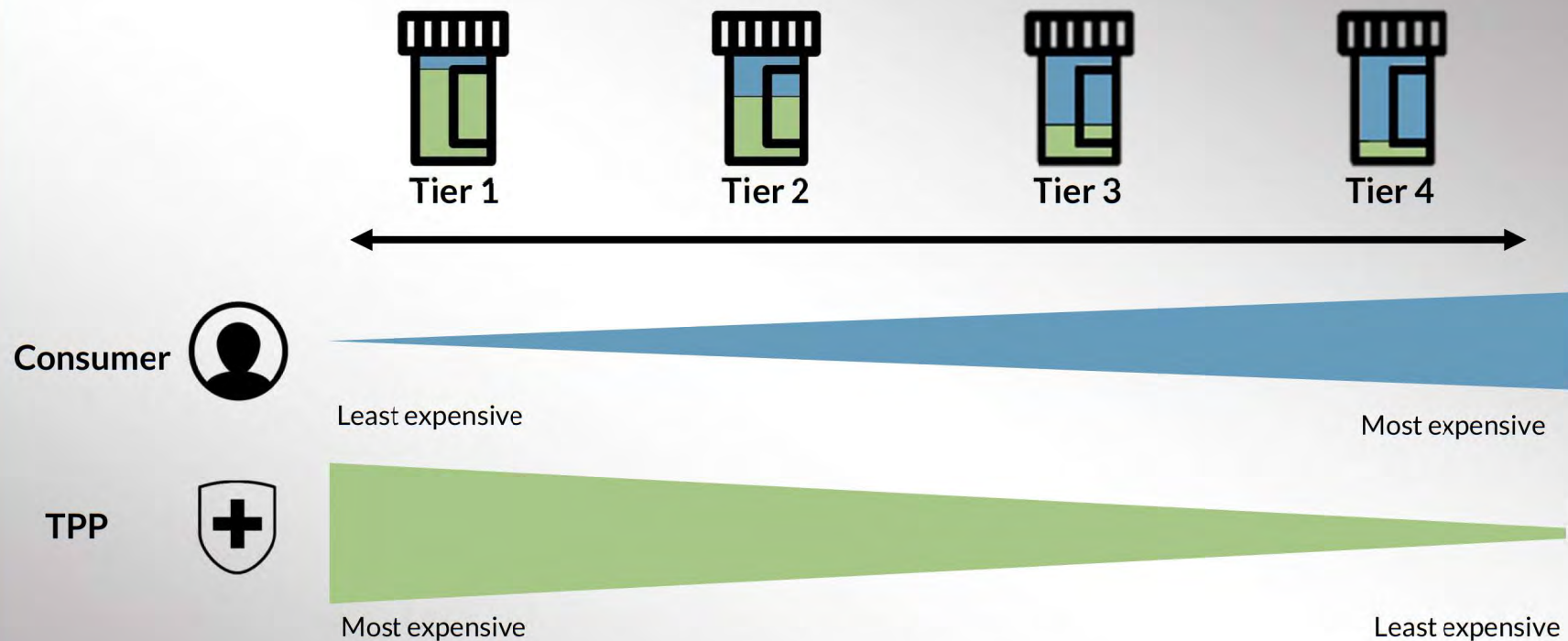
Evidence of Uninjured Class Members

Rebates and formulary placement can result in TPPs paying less for the brand than the generic



Source: Hughes Declaration, ¶ 13, Figure 1.

Plan and formulary design can result in TPPs paying less for the brand than the generic

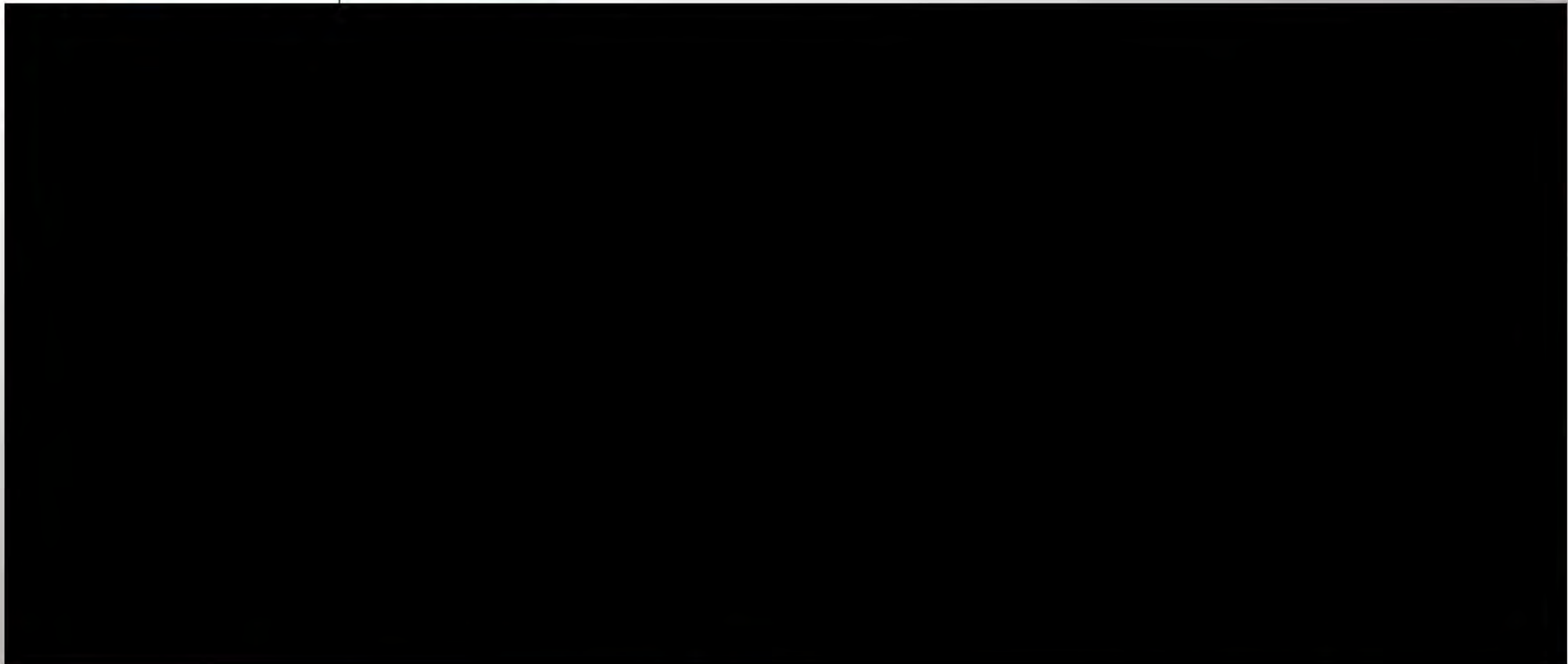


Generics are typically placed on low tiers to encourage use, while brands are placed on high tiers. As a result, TPPs frequently pay less for the brand than the generic.

Rebate payments are substantial and vary across Pharmacy Benefit Managers (PBMs)

Rebate
per Pill

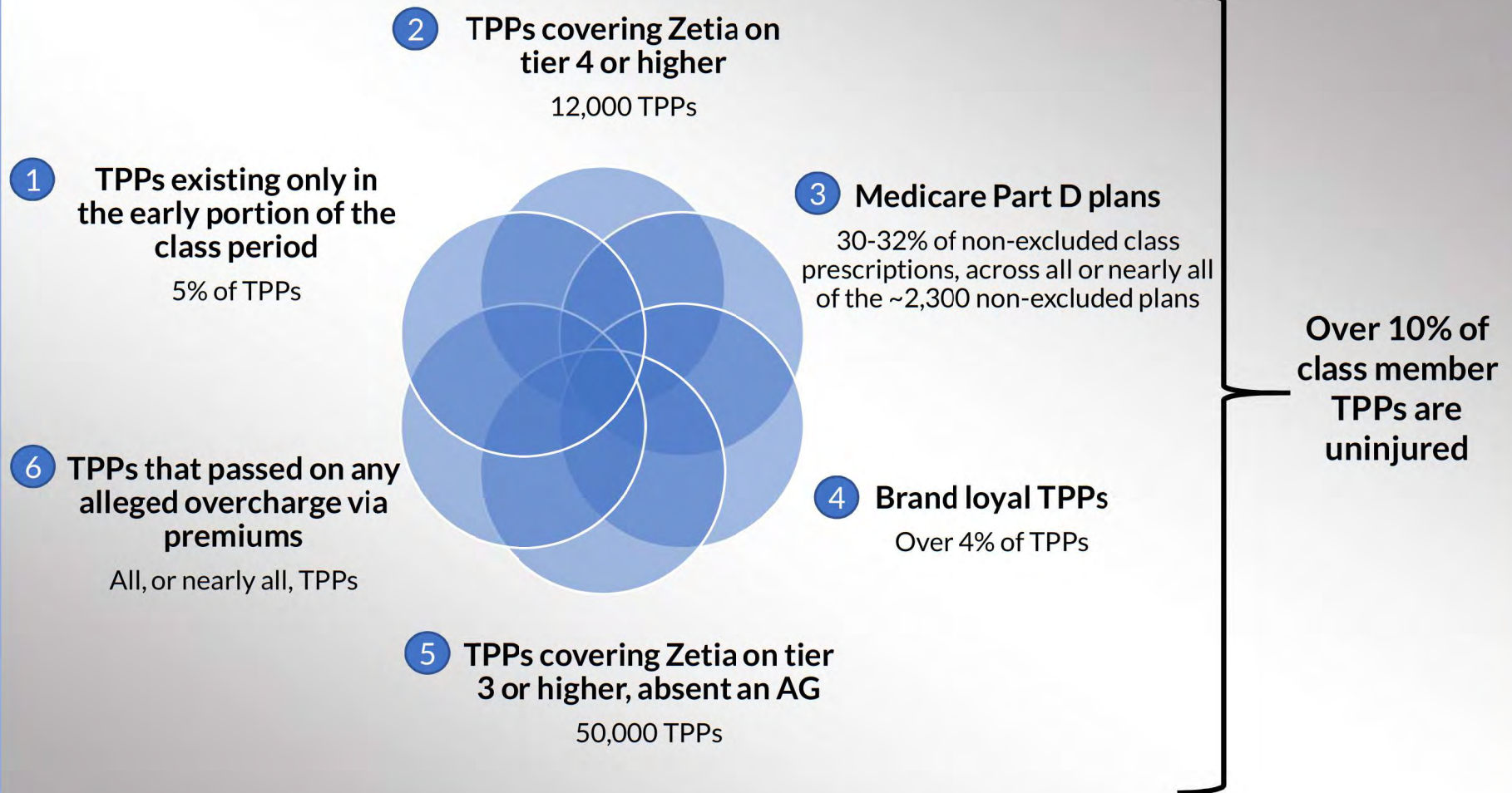
Dr. Lamb excludes the entities
receiving the highest rebates



Even after Dr. Lamb's exclusions, the [REDACTED] the brand price and
varies substantially across PBMs.

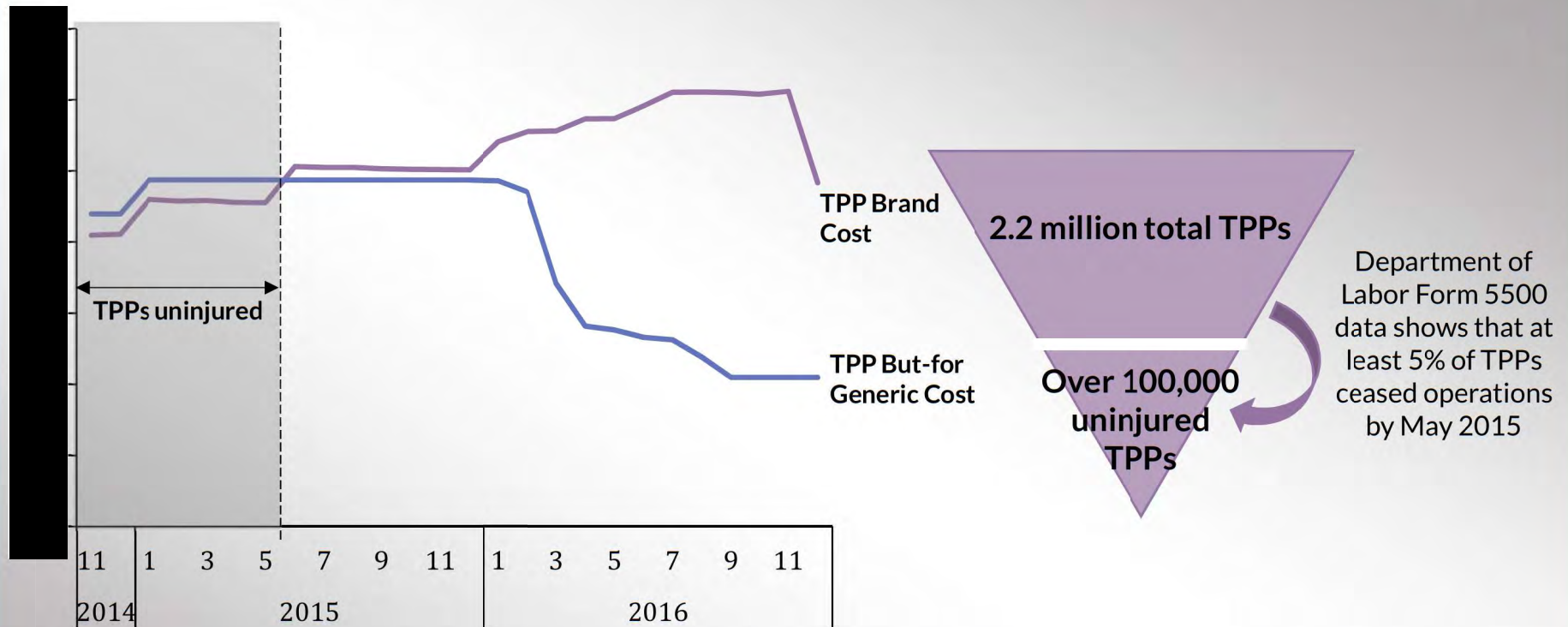
Source: Hughes Supplemental Declaration, ¶11, Exhibit 1 (Supplemental); Data: Merck rebates data.

Summary of examples of uninjured TPP class members



Source: Hughes Supplemental Declaration, ¶¶ 26-48.

TPPs that only purchased Zetia in the first portion of the class period are uninjured



Over 100,000 TPPs who ceased operations by May 2015 are uninjured.

1 Uninjured TPPs: Ceased Operations

2 Uninjured TPPs: Zetia on Tier 4

3 Uninjured TPPs: Medicare Part D

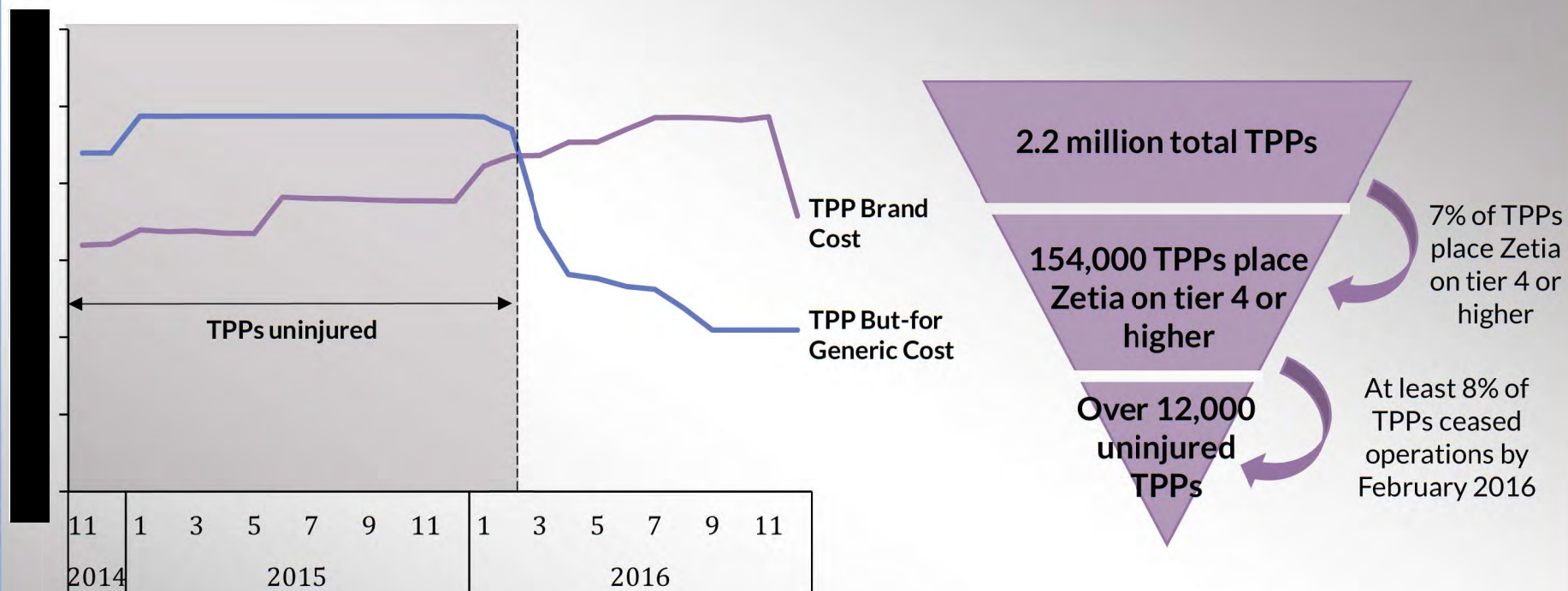
4 Uninjured TPPs: Brand Loyalty

5 Uninjured TPPs: No AG

6 Uninjured TPPs: Premiums

Source: Hughes Supplemental Declaration, ¶ 27, Exhibit 7 (Supplemental); Data: Dept. of Labor Form 5500.

TPPs with brand Zetia on tier 4 or higher would have paid more for generic Zetia for more than half of the class period



Over 12,000 TPPs that placed Zetia on tier 4 or higher and ceased operations by February 2016 are uninjured.

- 1 Uninjured TPPs: Ceased Operations
- 2 Uninjured TPPs: Zetia on Tier 4
- 3 Uninjured TPPs: Medicare Part D
- 4 Uninjured TPPs: Brand Loyalty
- 5 Uninjured TPPs: No AG
- 6 Uninjured TPPs: Premiums

Source: Hughes Supplemental Declaration, ¶ 28-31, Exhibit 9 (Supplemental); Data: MMIT, Dept. of Labor Form 5500.

Dr. Lamb's reply assertion that generic Zetia was not always placed on a generic tier is refuted by the evidence

Dr. Lamb claims that “evidence ... demonstrates that **PBM**s and **TPP**s often place generics in **non-preferred tiers** until additional generic competitors enter the market”

Lamb Reply Declaration, ¶ 50

2017 Aetna Pharmacy Drug Guide

colestipol hcl	Tier 1
CRESTOR	Tier 3
ezetimibe	Tier 1

https://clients.garnett-powers.com/pd/usc/downloads/tier3_formulary.pdf

[REDACTED]	
1/1/2017	
OSELTAMIVIR CAP 75MG	Tier 1
EZETIMIBE TAB 10MG	Tier 1
ZOVIA 1/50E TAB	Tier 1

Formularies available publicly and in case evidence show generic ezetimibe on tier 1 during Glenmark's exclusivity period.

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

6 Uninjured TPPs:
Premiums

Source: Dr. Hughes response to Lamb Reply Declaration.

Dr. Lamb's reply assertion that generic Zetia was not always placed on a generic tier is refuted by the evidence

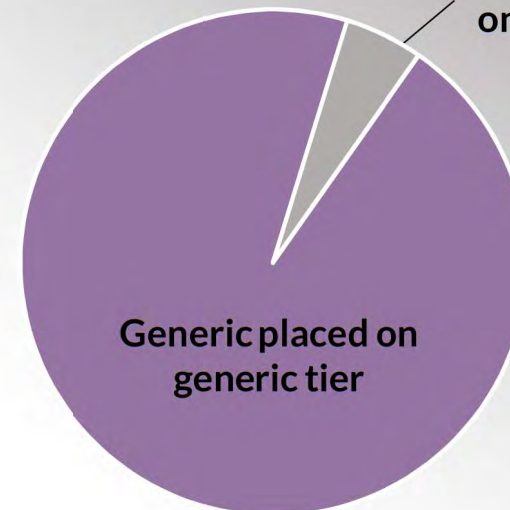
Generic Drugs

Retail 30-day supply:
\$5 **copayment**; mail
order: no charge

Preferred Brand Drugs

Retail 30-day supply:
\$10 **copayment**; mail
order: no charge if
requested by **Provider**;
\$10 **copayment** if not.

Generic not placed
on generic tier



Fill Date	Drug		Total Drug Cost	Total Quantity	Total Member Amount Paid
12/21/2016	EZETIMIBE	TAB 10MG	\$241.29	30	\$5.00
1/26/2017	EZETIMIBE	TAB 10MG	\$241.29	30	\$5.00
3/11/2017	EZETIMIBE	TAB 10MG	\$241.29	30	\$5.00
4/12/2017	EZETIMIBE	TAB 10MG	\$241.29	30	\$5.00
5/1/2017	EZETIMIBE	TAB 10MG	\$243.11	30	\$5.00
5/10/2017	EZETIMIBE	TAB 10MG	\$241.29	30	\$5.00
5/15/2017	EZETIMIBE	TAB 10MG	\$241.29	30	\$5.00
5/30/2017	EZETIMIBE	TAB 10MG	\$243.11	30	\$5.00
5/31/2017	EZETIMIBE	TAB 10MG	\$213.15	30	\$5.00

Named Plaintiff [REDACTED] put generic ezetimibe on a generic tier during Glenmark's exclusivity period.

Overall, MMIT data shows that **95% of TPPs placed generic ezetimibe on a generic tier** during Glenmark's exclusivity period.

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

6 Uninjured TPPs:
Premiums

Source: Dr. Hughes response to Lamb Reply Declaration; Data: Named Plaintiff claims data, MMIT.

Despite Dr. Lamb's claims, Merck documents and data show that TPPs placing Zetia on tier 4 did receive rebates

In 2016, [REDACTED] for Zetia on any tier, including the non-preferred tier

Product Name	NDC#	Strength	Package Size	Rebate Percentage				
				1 of 1 Product Status	1 of 2 Product Status	1 of 3 Product Status	Listed Formulary Status	Non Preferred Brand
ZETIA®	All NDCs	All Strengths	All Package Sizes	[REDACTED]				

MRKZETIA000944465, at 468

In 2014, all TPPs with [REDACTED] as their PBM received the same rebate for Zetia, regardless of what tier they placed it on

Rebates payments are not tied to specific tier placement. Manufacturers provide rebates for placement on the formulary itself and for avoiding prescribing restrictions.

① Uninjured TPPs: Ceased Operations

② Uninjured TPPs: Zetia on Tier 4

③ Uninjured TPPs: Medicare Part D

④ Uninjured TPPs: Brand Loyalty

⑤ Uninjured TPPs: No AG

⑥ Uninjured TPPs: Premiums

Source: Dr. Hughes response to Lamb Reply Declaration; Data: MMIT, Merck rebates data.

Despite Dr. Lamb's claims, Merck documents and data show that TPPs placing Zetia on tier 4 did receive rebates

PBM

Total Rebates for Zetia, 2014

PBM

Total Rebates for Zetia, 2014

Numerous examples exist of TPPs that placed Zetia on tier 4 and still received rebates. Even without rebates, many TPPs with Zetia on tier 4 would still be uninjured due to consumer cost sharing.

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

4 Uninjured TPPs:
Brand Loyalty

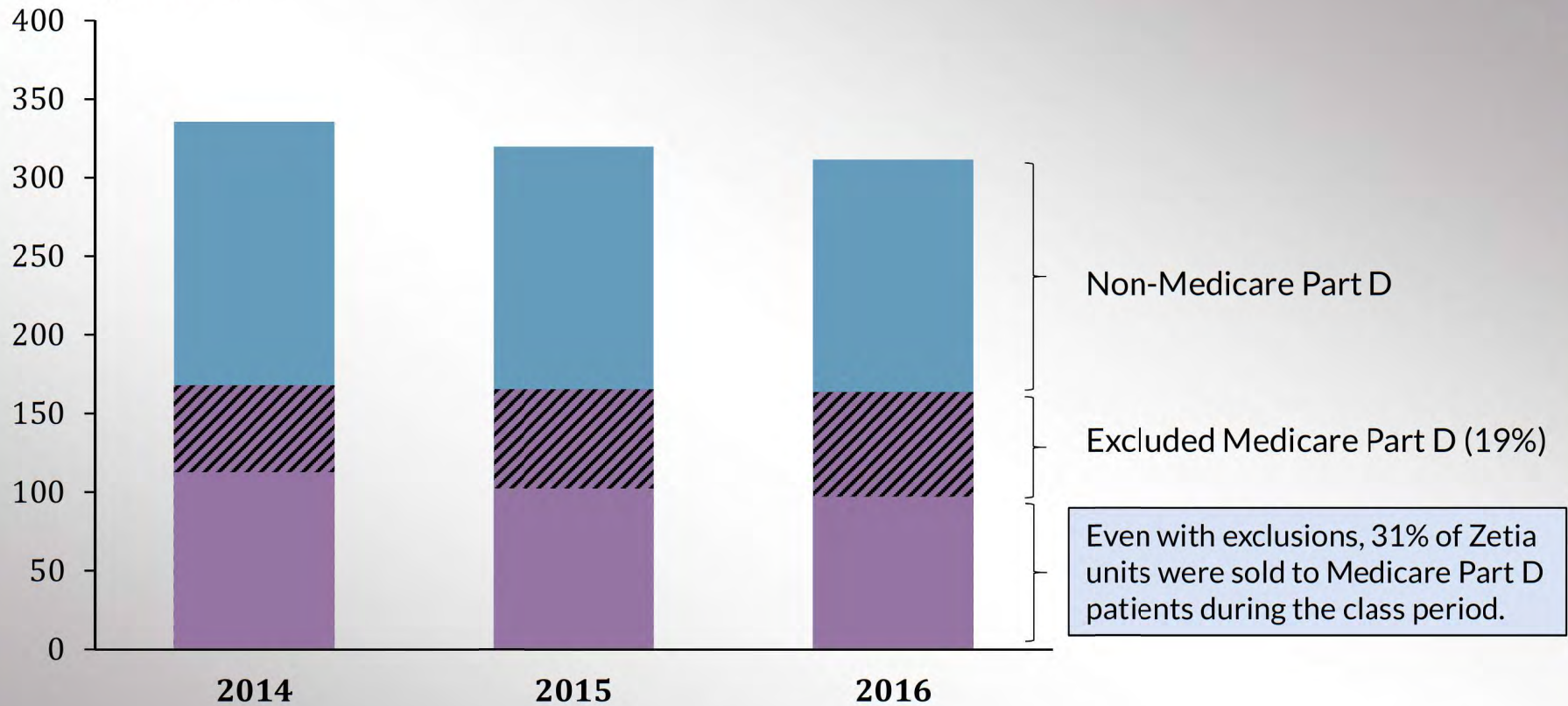
5 Uninjured TPPs:
No AG

6 Uninjured TPPs:
Premiums

Source: Dr. Hughes response to Lamb Reply Declaration; Data: MMIT, Merck rebates data.

Even after Dr. Lamb's exclusions, a large portion of Zetia purchases are made by Medicare Part D patients

Number of Zetia Units (Millions)

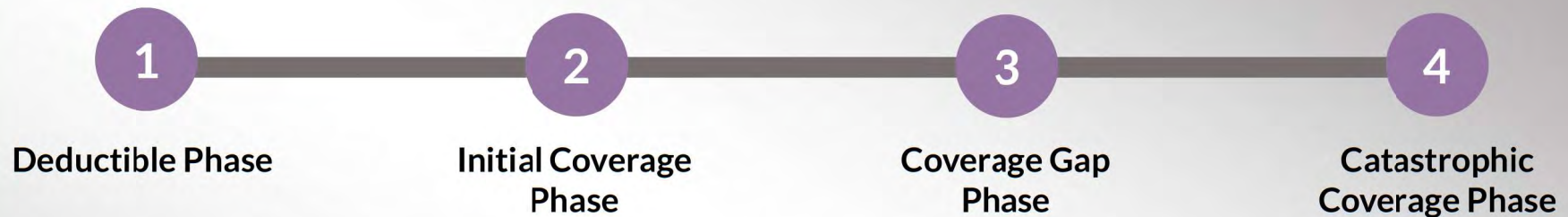


- ① Uninjured TPPs: Ceased Operations
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 ⑤ Uninjured TPPs: No AG
 ⑥ Uninjured TPPs: Premiums

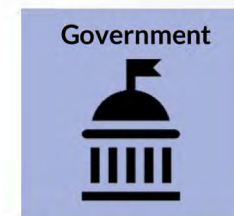
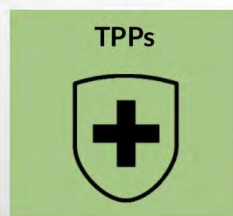
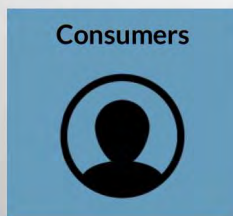
Source: Hughes Declaration, ¶ 132; Dr. Hughes response to Lamb Reply Declaration. Data: CMS, Merck rebates data.

Prescription drug spending under Medicare Part D is complex; plan responsibility depends on timing of the purchase

Prescription drug plan cost sharing varies depending on the coverage phase, which is defined by the level of consumer spending.



Four entities are responsible for Medicare Part D costs during at least one of the four phases.



1 Uninjured TPPs: Ceased Operations

2 Uninjured TPPs: Zetia on Tier 4

3 Uninjured TPPs: Medicare Part D

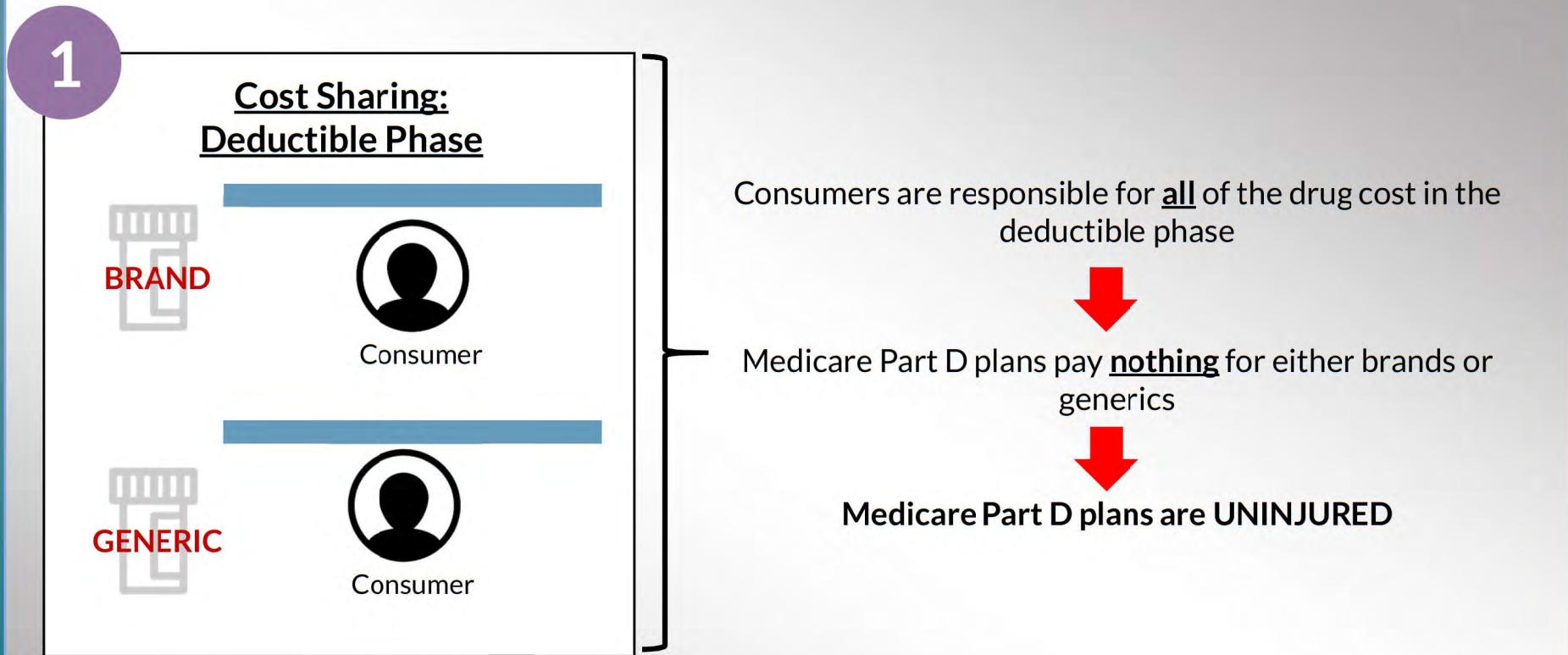
4 Uninjured TPPs: Brand Loyalty

5 Uninjured TPPs: No AG

6 Uninjured TPPs: Premiums

Source: Hughes Declaration, ¶¶ 68-73.

Dr. Lamb does not dispute that Medicare Part D plans are uninjured in the deductible phase



1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

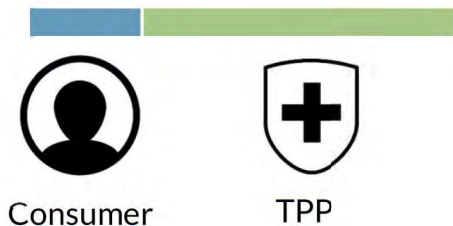
6 Uninjured TPPs:
Premiums

Source: Hughes Declaration, ¶¶ 69, 76.

The plan's financial responsibility in the initial coverage phase varies based on plan benefit design

2

Cost Sharing: Initial Coverage Phase



Plans share drug costs with consumers in the initial coverage phase



Generally the consumer copays or coinsurance amounts paid are higher for brands than for generics



Higher consumer copays/coinsurance for brand drugs, combined with manufacturer rebates, can make brand drugs cheaper than generics for plans

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

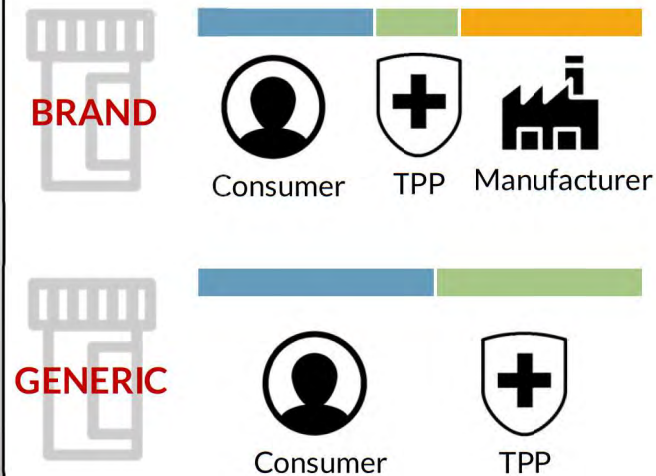
6 Uninjured TPPs:
Premiums

Source: Hughes Declaration, ¶¶ 70, 76.

Plans pay less for brand than generic in the coverage gap phase due to brand manufacturer discounts

3

Cost Sharing: Coverage Gap Phase



Drug manufacturers are mandated to pay for a substantial portion of brand drug costs in the coverage gap phase



Medicare Part D plans pay very little for brand drugs



Low payments for brand drugs can make brand drugs cheaper than generics for plans

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

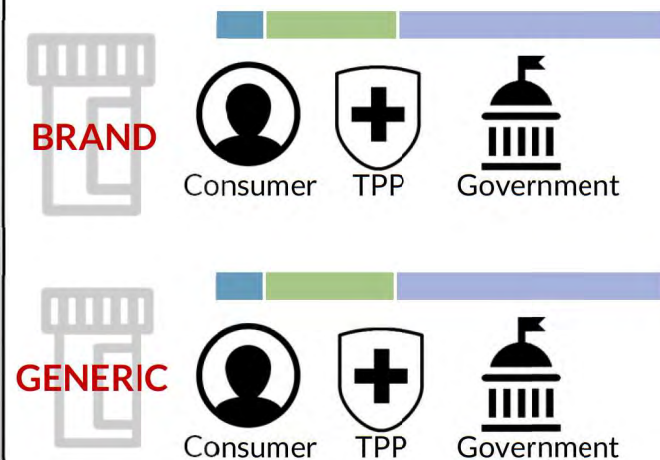
6 Uninjured TPPs:
Premiums

Source: Hughes Declaration, ¶¶ 71, 76.

The federal government is responsible for the majority of drug costs in the catastrophic coverage phase

4

Cost Sharing: Catastrophic Coverage Phase



The federal government covers most of both brand and generic drug costs in the catastrophic coverage phase



Medicare Part D plans pay very little for brand drugs



Low payments for brand drugs, combined with manufacturer rebates, can make brand drugs cheaper than generics for plans

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

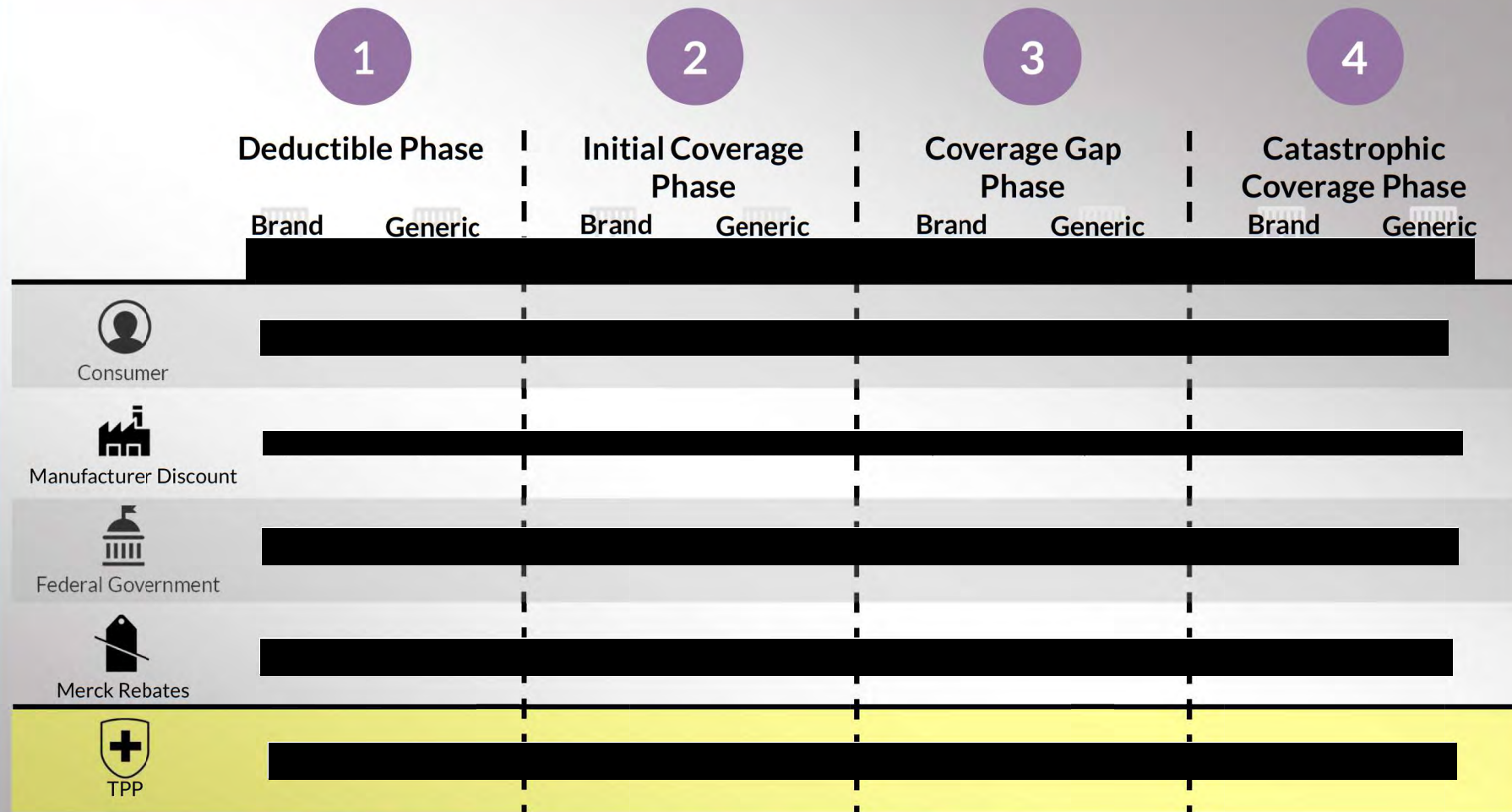
4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

6 Uninjured TPPs:
Premiums

Source: Hughes Declaration, ¶¶ 72, 76.

The average Medicare Part D plan is uninjured in all four coverage phases at the mid-point of the class period



1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

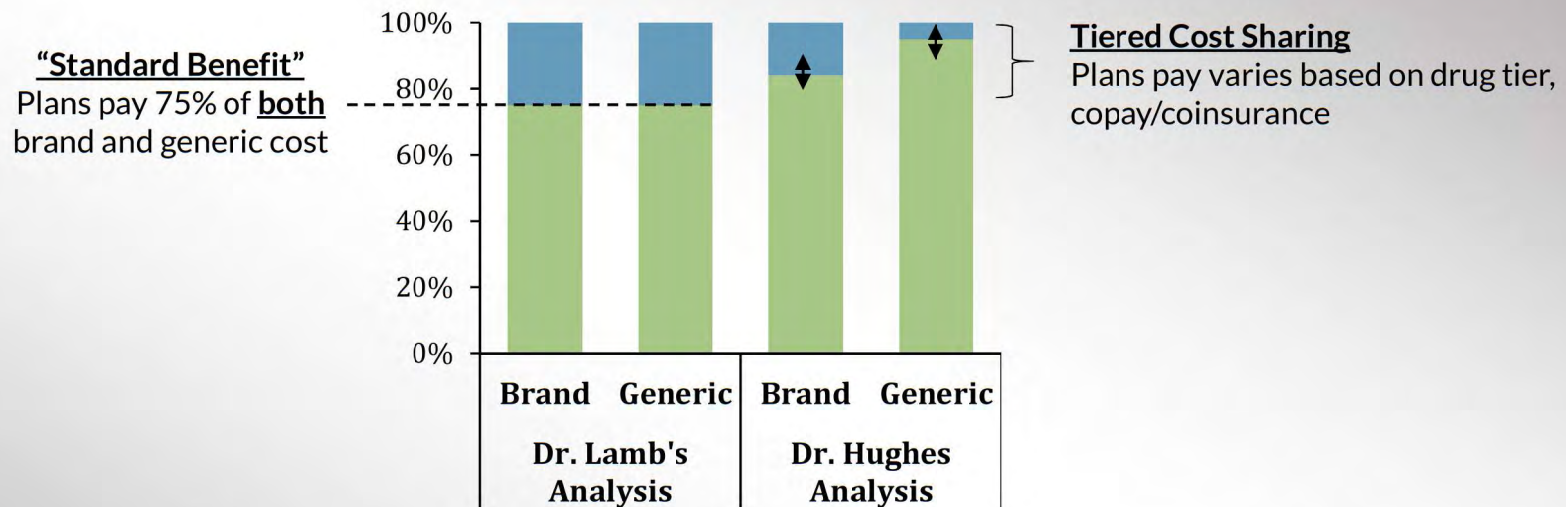
6 Uninjured TPPs:
Premiums

Source: Hughes Supplemental Declaration, ¶¶ 39-40, Exhibit 11 (Supplemental); Data: Lamb Trial Declaration backup, KFF and Q1 Medicare cost sharing data. 19

Dr. Lamb's analysis of injury in the initial coverage phase is not representative of virtually any Medicare Part D plan

"I find that, net of cost-sharing and rebates, Medicare Part D plans were injured in the initial coverage phased [sic] during every month in the Class Period."

Lamb Reply Declaration, ¶ 42



"In 2016...no plans will offer the defined standard benefit...Most plans will charge tiered copayments for covered drugs rather than 25% coinsurance."

Kaiser Family Foundation, "The Medicare Part D Prescription Drug Benefit," October 2015

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

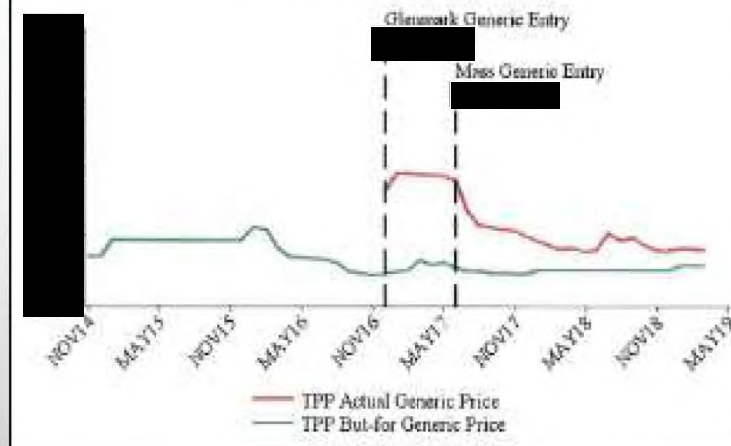
6 Uninjured TPPs:
Premiums

Source: Dr. Hughes response to Lamb Reply Declaration; Data: Tiered cost sharing from KFF, "Medicare Part D in 2016 and Trends over Time," Sept. 2016.

Dr. Lamb's analysis confirms that Medicare Part D plans are not injured in the coverage gap phase

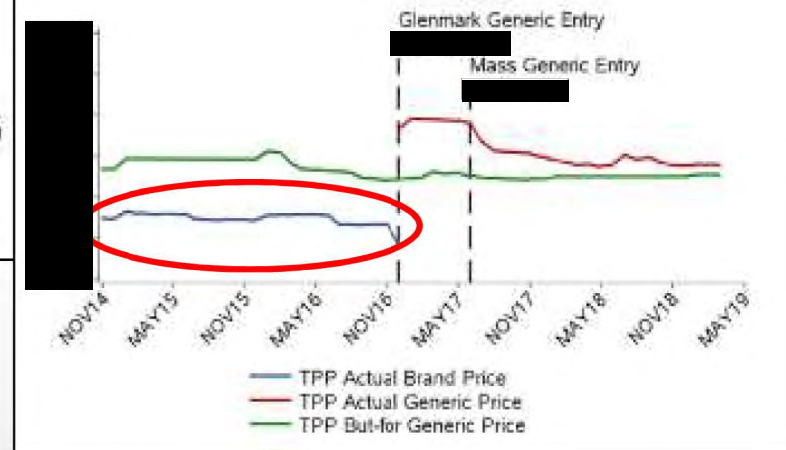
REPLY DECLARATION OF DR. RUSSELL L. LAMB, PH.D.

Figure 2
Medicare Part D Actual and But-for Prices
Coverage Gap Phase



TPP Actual Brand Price is missing

Amended Figure 2
Medicare Part D Actual and But-for Prices
Coverage Gap Phase



Based on Dr. Lamb's own data, **TPP Actual Brand Price** is lower than **TPP But-For Generic Price**

NO INJURY

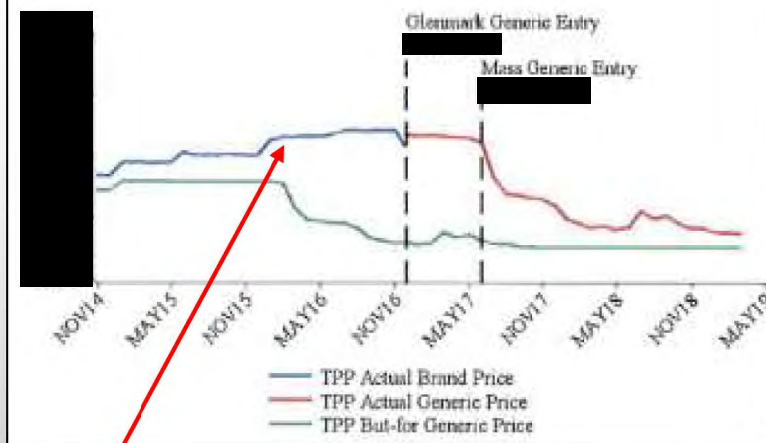
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|-------------------------------------|-----------------------------------|-----------------------------------|---------------------------------|-------------------------|----------------------------|
| 1 Uninjured TPPs: Ceased Operations | 2 Uninjured TPPs: Zetia on Tier 4 | 3 Uninjured TPPs: Medicare Part D | 4 Uninjured TPPs: Brand Loyalty | 5 Uninjured TPPs: No AG | 6 Uninjured TPPs: Premiums |
|-------------------------------------|-----------------------------------|-----------------------------------|---------------------------------|-------------------------|----------------------------|

Source: Dr. Hughes response to Lamb Reply Declaration; Data: Lamb Reply Declaration backup.

Once corrected, Dr. Lamb's analysis reveals no injury in the catastrophic coverage phase

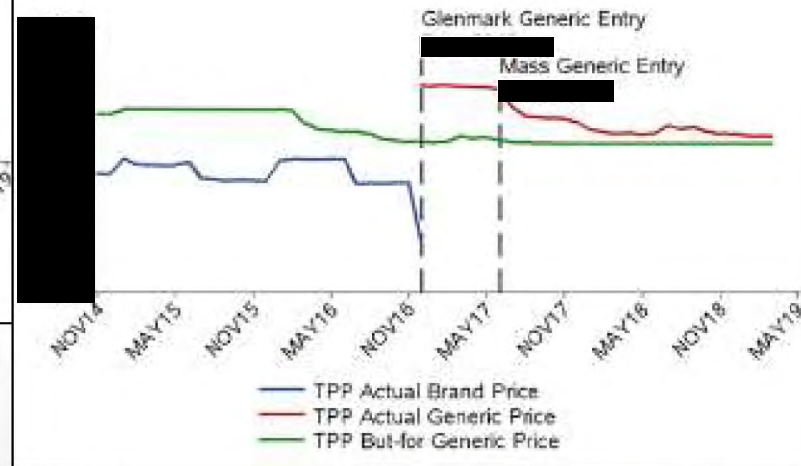
REPLY DECLARATION OF DR. RUSSELL L. LAMB, PH.D.

Figure 3,
Medicare Part D Actual and But-for Prices
Catastrophic Phase



Dr. Lamb incorrectly attributes **only 15%** of rebates to Medicare Part D plans, thus overstating the **TPP Actual Brand Price**

Amended Figure 3
Medicare Part D Actual and But-For Prices
Catastrophic Phase



Once corrected: **TPP Actual Brand Price** is lower than **TPP But-For Generic Price**

NO INJURY

1 Uninjured TPPs: Ceased Operations

2 Uninjured TPPs: Zetia on Tier 4

3 Uninjured TPPs: Medicare Part D

4 Uninjured TPPs: Brand Loyalty

5 Uninjured TPPs: No AG

6 Uninjured TPPs: Premiums

Source: Dr. Hughes response to Lamb Reply Declaration; Data: Lamb Reply Declaration backup.

Brand loyal TPPs are uninjured

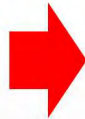
Dr. Lamb acknowledges that brand loyal TPPs exist and must be removed



“Brand loyalists, if any, would have accounted for no more than **2 percent** of the proposed Class.”

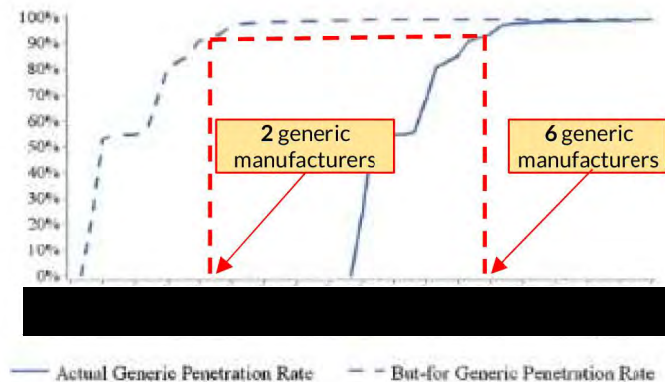
Lamb Reply Declaration, ¶ 38 (emphasis added)

Dr. Lamb overestimates generic penetration in the but-for world and thus underestimates TPP brand loyalty



TRIAL DECLARATION OF DR. RUSSELL L. LAMB, PH.D.

Figure 6
Actual and But-for Generic Ezetimibe Penetration Rate
But-for Generic Entry in November 2014



Based on generic penetration rates presented in Dr. Lamb’s cited literature, **at least 4 percent** of TPPs would have been brand loyal in the but-for world.

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

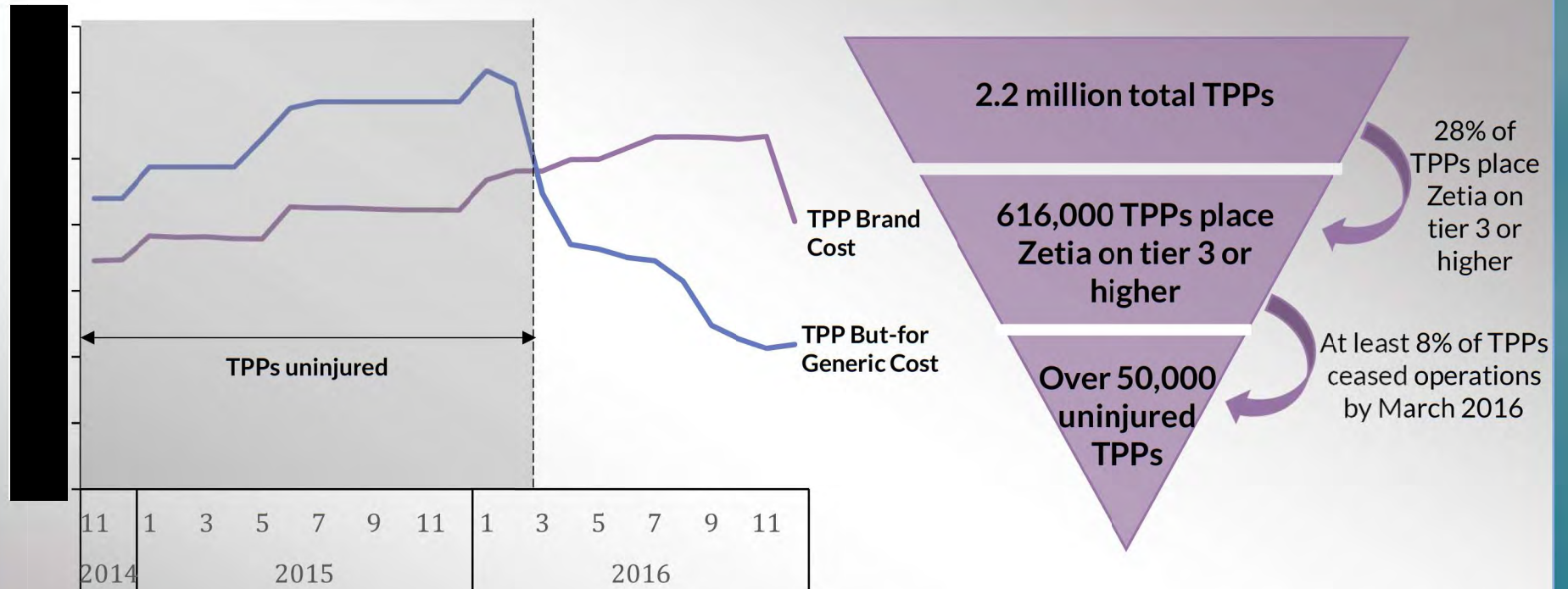
4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

6 Uninjured TPPs:
Premiums

Source: Hughes Declaration, ¶¶ 79-85; Data: Form 5500, Berndt, E. et al., "Authorized Generic Drugs, Price Competition, and Consumers' Welfare," May 2007. 23

Without an authorized generic, TPPs with Zetia on tier 3 or higher are uninjured for more than half of the class period



Over 50,000 TPPs that placed Zetia on tier 3 or higher and ceased operations by March 2016 are uninjured.

- | | | | | | |
|--|--------------------------------------|--------------------------------------|------------------------------------|----------------------------|-------------------------------|
| 1 Uninjured TPPs:
Ceased Operations | 2 Uninjured TPPs:
Zetia on Tier 4 | 3 Uninjured TPPs:
Medicare Part D | 4 Uninjured TPPs:
Brand Loyalty | 5 Uninjured TPPs:
No AG | 6 Uninjured TPPs:
Premiums |
|--|--------------------------------------|--------------------------------------|------------------------------------|----------------------------|-------------------------------|

Source: Hughes Supplemental Declaration, ¶¶ 32-36, Exhibit 15 (Supplemental); Data: MMIT, Dept. of Labor Form 5500.

Dr. Lamb's assumption that Merck would have launched an authorized generic in November 2014 is speculative

[REDACTED]

MRKZETIA000600509-512, at 511

A Merck presentation from 2014 discusses the possibility of launching an authorized generic [REDACTED]

MRKZETIA_R000025624-687, at 629

Merck documents cited by Dr. Lamb consider a market with multiple generic manufacturers, rather than the limited entry scenario he models.

Dr. Lamb's cited documents also show that under different market conditions, such as fewer generic entrants, an authorized generic is not always the optimal strategy.

"Under different conditions...not authorizing an AG would maximize revenue"

MRKZETIA_R000090757, p. 22

"ZETIA Rx/OTC switch represents promising opportunity to maximize brand value post-LOE in the US."

MRKZETIA_R000025624, at 660

1 Uninjured TPPs:
Ceased Operations

2 Uninjured TPPs:
Zetia on Tier 4

3 Uninjured TPPs:
Medicare Part D

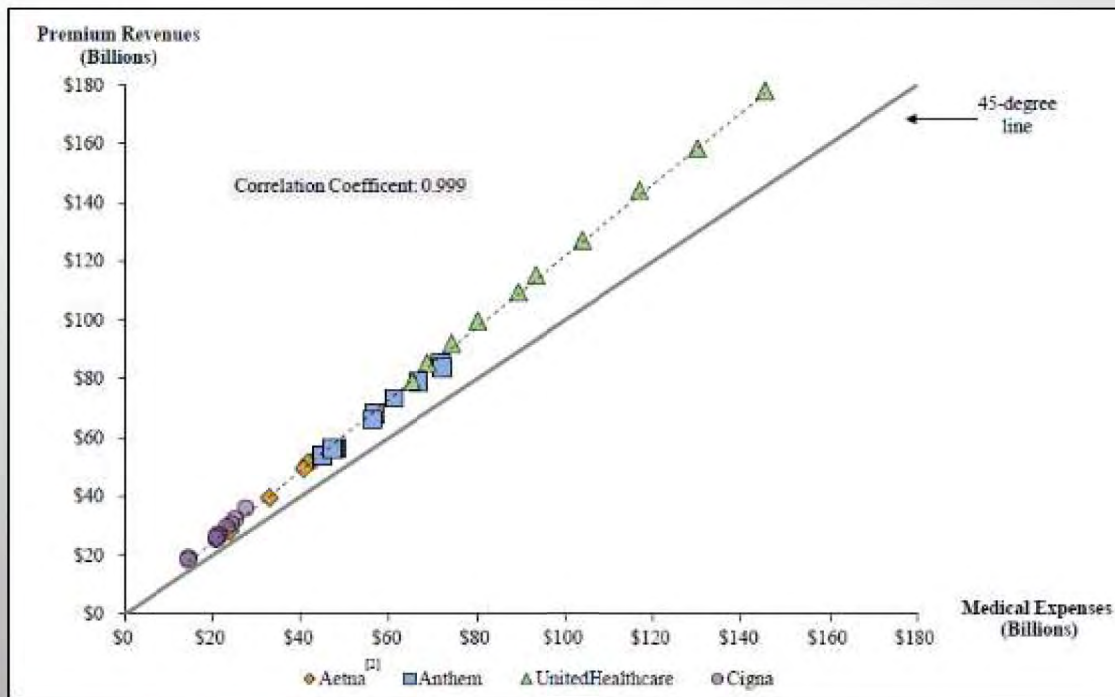
4 Uninjured TPPs:
Brand Loyalty

5 Uninjured TPPs:
No AG

6 Uninjured TPPs:
Premiums

Source: Dr. Hughes response to Lamb Reply Declaration.

All, or almost all, TPPs would have passed on any alleged overcharge to consumers through premiums



The four largest health insurers in the U.S. charge consumers more as their costs increase



TPPs that charged consumers for any alleged overcharge are uninjured.

- 1 Uninjured TPPs: Ceased Operations
- 2 Uninjured TPPs: Zetia on Tier 4
- 3 Uninjured TPPs: Medicare Part D
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- 5 Uninjured TPPs: No AG
- 6 Uninjured TPPs: Premiums

Source: Hughes Declaration, ¶¶ 86-91, Exhibit 14; Data: SEC 10-K filings and Annual Reports.



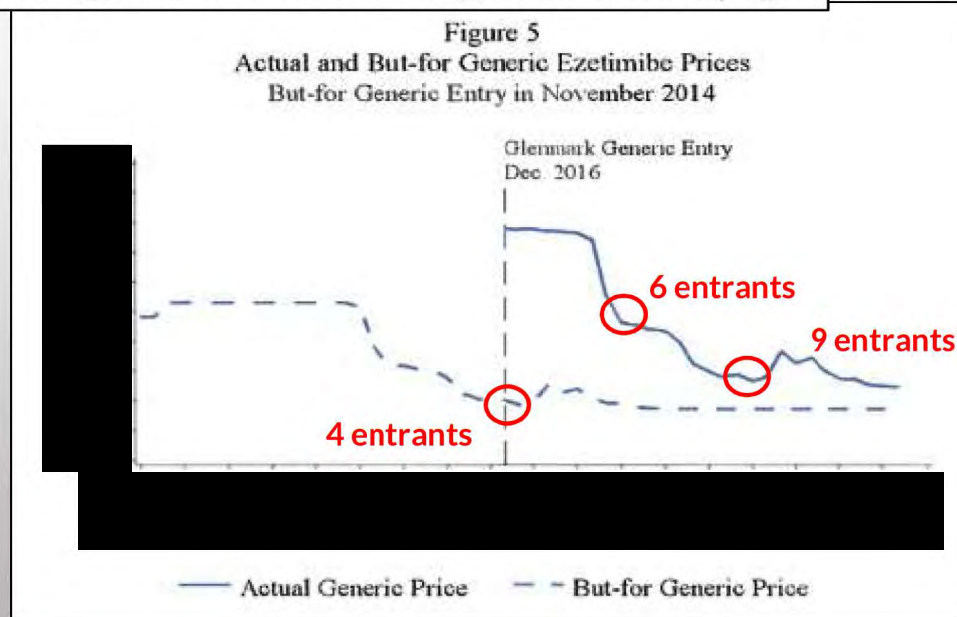
Generic-Generic Damages

Dr. Lamb overstates generic-generic (“G-G”) injury through flawed assumptions regarding but-for generic prices

“From February 2016 through March 2019 [...] I allow the but-for generic ezetimibe price to move in the same way it did in the actual world after mass generic entry in June 2017.”

Lamb Trial Declaration, ¶ 75 (emphasis added)

TRIAL DECLARATION OF DR. RUSSELL L. LAMB, PH.D.



Dr. Lamb’s assumption that the but-for world will mimic the actual world causes him to estimate but-for generic price with 4 entrants is less than the actual world price with 9 generic entrants.

The fact that Dr. Lamb finds G-G injury more than two years after the end of the alleged conduct highlights his methodology’s disconnect from any reasonable theory of harm.